

Registered pharmacy inspection report

Pharmacy Name: Rigbys Pharmacy, 14 Swan Lane, Bolton, Greater Manchester, BL3 6TL

Pharmacy reference: 9010830

Type of pharmacy: Community

Date of inspection: 01/09/2020

Pharmacy context

This community pharmacy is located next to a medical centre on the corner of a busy road and it serves a diverse range of people. The pharmacy dispenses NHS prescriptions and it sells a range of over-the-counter medicines. This was a targeted inspection as information had been received that the pharmacy had been obtaining an unusually large quantity of codeine linctus, which is addictive and liable to abuse and misuse. The inspection was undertaken during the Covid-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy does not have adequate systems to identify and manage the risks when selling codeine linctus which is liable to abuse, overuse or misuse.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy sells large amounts of codeine linctus without making appropriate checks to safeguard against misuse.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy does not identify and manage the risks in relation to the sales of codeine linctus. This means that there are some risks to patient safety and vulnerable people might be able to obtain medicines that could cause them harm. The pharmacy's working practices in relation to other services, including the supply of prescriptions, are generally safe. And the pharmacy team members work to professional standards and are clear about their roles and responsibilities. They understand how to keep people's private information safe and ask people who use the pharmacy for their views and feedback.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs) for the services provided, with signatures showing that all members of the pharmacy team had read and accepted them. Roles and responsibilities were set out in SOPs and the pharmacy team members were performing duties which were in line with their role. The name of the responsible pharmacist (RP) was displayed as per the RP regulations.

The pharmacy manager had worked full time in the pharmacy for around eight years. He said there was a high demand for codeine linctus over-the-counter (OTC) which had increased over the last year, and there had been a surge in demand in the last six months. He believed the high number of requests were because the pharmacy was in a busy part of town with a high footfall, and it was the only pharmacy in the area which sold codeine linctus. He thought that the recent increase may have been due to covid-19, as more people were concerned about coughs. He estimated that the pharmacy received around ten to twelve requests for codeine linctus each day, either by telephone or in person. He said a diverse range of people requested it and he wouldn't sell it if he had seen the person requesting it before, unless three or four months had passed, and he felt that another supply was genuinely required. He stated that he asked the 'WWHAM' questions and made a professional decision each time. He said that he would only sell codeine linctus if it was for a dry cough and he would ask the person why they specifically wanted codeine. He said he would not sell it if he felt the person was abusing it or taking it for anything other than a dry cough. He said he never recommended it if it wasn't asked for by name, and he would not sell it to a representative, in case they were buying it for somebody who wasn't genuine. He estimated that he authorised around four or five sales of codeine linctus each day and would tell the person that it was addictive and shouldn't be taken for more than three days. Considering the unusually large number of requests for codeine linctus and the high volume of sales, there was nothing in place to monitor these and no written records of the sales or refusal of sales for codeine linctus. This was a risk as there was no way of capturing and sharing information with the superintendent pharmacist (SI) or other members of the pharmacy team. The pharmacy manager said information about codeine sales was not recorded on the patient's medication record (PMR) as people purchasing codeine linctus were not usually regular patients at the pharmacy, so they did not have a PMR. He had not raised a concern or had any communication with the SI about the sale of codeine linctus and had not sought advice about monitoring or auditing the sales.

At the end of the inspection, the pharmacy manager told the inspector that he had decided to stop selling codeine linctus in the pharmacy. And later that day he sent the inspectors photographs of posters, which were on display in the pharmacy advising people the pharmacy did not keep codeine

linctus. There were also leaflets explaining to people who wanted codeine linctus that they should contact their doctor, or if necessary the local drug and alcohol service.

The pharmacy manager confirmed he had considered the risks of coronavirus for the pharmacy team and people using the pharmacy. He had introduced several steps to ensure social distancing and infection control and had completed individual staff risk assessments.

Dispensing incidents were reported and learning points were included. There weren't any recent incident reports, but the pharmacy manager confirmed there had not been any recent errors. Near misses were reported and discussed with the pharmacy team. Actions were taken to prevent reoccurrences. For example, a 'Check formulation' alert note was in front of aspirin and a 'Check strength' alert note was in front of Clenil inhalers, following near misses with these medications

A notice was on display in the pharmacy advertising the complaint procedure, with the details of who to complain to and how to leave feedback, comments or suggestions. A customer satisfaction survey was carried out annually. A current certificate of professional indemnity insurance was on display in the pharmacy. Private prescription records, the RP record, and the controlled drug (CD) register were appropriately maintained. Records of CD running balances were kept and these were regularly audited. Patient returned CDs were recorded and disposed of appropriately.

Staff signed confidentiality agreements as part of their terms of employment. Confidential waste was collected in a designated place and shredded. Assembled prescriptions and paperwork containing patient confidential information were stored appropriately so that people's details could not be seen by members of the public.

The pharmacy manager had completed the Centre for Pharmacy Postgraduate Education (CPPE) level 2 training on safeguarding and there were safeguarding SOPs which the pharmacy team had read. The pharmacy had a chaperone policy, and this was highlighted to people.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to manage its workload. Team members have the right qualifications for the jobs they do and work well together. They are comfortable providing feedback to their manager and they receive feedback about their own performance. Team members have opportunities to discuss issues informally together.

Inspector's evidence

The pharmacy manager was working as the RP and there was a preregistration pharmacist and four NVQ2 qualified dispensers (or equivalent) on duty at the time of the inspection. Two delivery drivers were also part of the pharmacy team. The staffing level was adequate for the volume of work during the inspection and the team were observed working collaboratively with each other and the patients. Absences were covered by re-arranging staff hours or transferring staff from neighbouring branches in the area. The pharmacy's workload had increased as a result of the pandemic and the team said they had all been well throughout. The staff present at the inspection appeared to be enthusiastic and competent in the services they were carrying out. Certificates were displayed indicating that all of the team members had completed accredited courses. They completed additional training modules on an electronic tablet provided by Alphega, to ensure their knowledge was up to date. Team members admitted they had not carried out much training on the tablet in recent months due to the additional workload. The pharmacy manager had been appropriately trained for the flu vaccination service which the pharmacy was going to soon start.

Pharmacy team members were given formal appraisals where performance and development were discussed and received positive and negative feedback informally from the pharmacy manager. Informal team meetings were held where a variety of issues were discussed, and concerns could be raised. The team used WhatsApp to send work related messages to each other, taking care not to include patient details. A dispenser said she felt there was an open and honest culture in the pharmacy and said the staff could make suggestions or criticisms informally. She said she would report any concerns she might have to the pharmacy manager.

The pharmacist said he felt empowered to exercise his professional judgement and could comply with his own professional and legal obligations. For example, refusing to sell codeine linctus if he didn't feel it was appropriate. He said he was not under any pressure from the pharmacy's owners to sell codeine linctus.

Principle 3 - Premises ✓ Standards met

Summary findings

The premises provide a professional environment for people to receive healthcare services. The pharmacy has a private consultation room that enables it to provide members of the public with the opportunity to have confidential conversations.

Inspector's evidence

The pharmacy premises, including the shop front and fascia were clean and well maintained. The retail area was free from obstructions, professional in appearance and had a waiting area with two chairs. There were information notices about Covid-19, and reminders of the requirement to maintain social distancing. Extra cleaning had been introduced and was recorded on a chart. Touch surfaces, such as the door handles were cleaned twice a day. The temperature and lighting were adequately controlled. The pharmacy was fitted out to a good standard, and the fixtures and fittings were in good order. Maintenance problems were reported to the company's handyman and the response time was appropriate to the nature of the issue.

There were three separate stockrooms on the first floor where excess was stored. Staff facilities included a WC with a wash hand basin and hand wash. The hot water tap had broken the previous week, and the handyman had been informed. There was a separate dispensary sink for medicines preparation with hot and cold running water. The consultation room was uncluttered, clean and professional in appearance. The availability of the room was highlighted by a sign on the door. This room was used when carrying out services such as vaccinations and when customers needed a private area to talk.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy orders unusually large amounts of codeine linctus, but it cannot explain why it sells so much, or demonstrate that suitable safeguards are in place to make sure sales are safe and appropriate. This is a patient safety risk because people's conditions might not be properly monitored, and their use of medication may not be appropriately controlled. The pharmacy offers a range of other healthcare services, which are generally well managed, so people receive appropriate care. It gets its medicines from licensed suppliers and the team carries out some checks to ensure medicines are in suitable condition to supply.

Inspector's evidence

There was a step up to the front door of the pharmacy, but it was possible for customers to enter with prams and wheelchair users with assistance. Some of the services provided by the pharmacy were displayed in the window of the pharmacy along with the opening hours. The pharmacy team were clear what services were offered and where to signpost people to a service not offered. Signposting information which could be used to inform people of services and support available elsewhere was kept in the consultation room.

The pharmacy offered a repeat prescription ordering service and people were contacted before their prescriptions were due each month, to check their requirements. This was to reduce stockpiling and medicine wastage. There was a home delivery service with associated audit trail.

Space was quite limited in the dispensary, but the workflow was organised into separate areas with a designated checking area. The dispensary shelves were well organised, neat and tidy. Dispensed by and checked by boxes were initialled on the medication labels to provide an audit trail. Different coloured baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. The baskets were stacked to make more bench space available.

The team were aware of the valproate pregnancy prevention programme. An audit had been carried out and none of the regular patients were in the at-risk group. The pharmacy manager could not locate the valproate information pack and care cards, so there was a risk that any new patients in the at-risk group might not be given the appropriate information and counselling. One of the dispensers pointed out that most packs of Epilim contained the care cards and the pharmacy manager said he would print off relevant information if necessary.

The pharmacy manager said in addition to codeine linctus, the pharmacy received a lot of requests for other medicines liable to abuse such as Phenergan and pseudoephedrine containing products. The details of these medicines and what actions the pharmacy team should take when these were requested were not outlined in the pharmacy's SOPs for OTC medicines. The pharmacy manager said the team knew to refer these requests to him. A dispenser, who had worked at the pharmacy for around seven years, and regularly covered the medicine counter, explained what questions she asked when making a medicine sale and confirmed that she would always refer requests for codeine containing products and other medicines which could be abused, such as Phenergan, to the RP. There was only one bottle of Phenergan on display and the pharmacy manager said they only sold one or two bottles of this each month.

Around fifty people received their medication in multi-compartment compliance aid packs and the pharmacy had continued to provide this service throughout the pandemic. There was a SOP which detailed an assessment as to the appropriateness of a compliance aid pack for patients requesting a compliance aid pack. The pharmacy manager said he would complete an informal assessment but usually the request was made by the patient's GP practice and he assumed they had already carried out an assessment.

CDs were stored in two CD cabinets which were securely fixed to the wall. The keys were under the control of the responsible pharmacist during the day. Date expired and patient returned CDs were segregated and stored securely. Patient returned CDs were destroyed using denaturing kits. Pharmacy medicines were stored behind the medicine counter so that sales could be controlled. There were 17 bottles of 200ml Pinewood sugar free codeine linctus in a box on a shelf beneath the medicine counter. They were out of reach and sight of the public. The pharmacy manager explained that because of the increase in requests for codeine linctus he made the decision to move it to a shelf beneath the medicine counter around six months ago, so it could not be seen by the public. In this way, if he decided to refuse the sale, he could tell the person requesting it, that they didn't have any in stock. He said this was necessary because some people 'kicked off' when they were refused the sale. There were an additional ten 200ml bottles in one of the stockrooms on the first floor, which a dispenser confirmed was part of a recent order of 40 in August 2020. She said she placed the orders monthly for the pharmacy and she usually ordered 20 or 40 bottles every month, although some months none were ordered, if they had enough in stock. Another dispenser confirmed that they occasionally received NHS prescriptions for codeine linctus, although she could not recall the name of any of the patients. The pharmacy manager recalled one person who received it on prescription. He displayed the patient medication record (PMR), and the patient had two 200ml bottles during 2020, one in 2019 and one in 2018. The pharmacy manager could not recall the name of any other patient who received codeine linctus on prescription. There was a two litre stock bottle of codeine linctus in the dispensary, but the pharmacy manager said 200ml bottles were usually used for prescriptions. He said they did not usually supply other pharmacy's with stock, so the majority of the codeine linctus ordered was sold from the pharmacy.

Recognised licensed wholesalers were used to obtain medicines. Medicines were stored in their original containers at an appropriate temperature. Date checking was carried out and documented. Short dated stock was highlighted. Expired medicines were segregated and placed in designated bins.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

Members of the pharmacy team have the equipment and facilities they need for the services they provide. They maintain the equipment so that it is safe and use it in a way that protects privacy.

Inspector's evidence

Team members generally wore face masks when working in the pharmacy. The pharmacy manager was not wearing a face mask but said he would if he carried out any face-to-face communication with people. There was a clear protective screen at the medicine counter and hand sanitizer gel to help with infection control.

Current versions of the British National Formulary (BNF) and BNF for children were available and the pharmacist could access the internet for the most up-to-date information. There was a large clean medical fridge. The minimum and maximum temperatures were being recorded regularly and had been within range throughout the previous month. All electrical equipment appeared to be in good working order.

There was a selection of clean glass liquid measures with British standard and crown marks. Separate measures were marked and used for methadone solution. The pharmacy had a range of clean equipment for counting loose tablets and capsules, with a separately marked tablet triangle that was used for cytotoxic drugs. Medicine containers were appropriately capped to prevent contamination.

Computer screens were positioned so that they weren't visible from the public areas of the pharmacy. Patient medication records (PMRs) were password protected. Cordless phones were available in the pharmacy, so staff could move to a private area if the phone call warranted privacy.

What do the summary findings for each principle mean?

Finding	Meaning
✓ Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✓ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✓ Standards met	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.